K021906

SEP 4 2002

510(k) Summary

1.	Name:	Quinton Inc
2.	Address:	3303 Monte Villa Parkway Bothell, WA 98021-8906
3.	Phone number:	(425) 402-2255
4.	Fax number:	(425) 402-2017
5.	Contact person:	Karen Browne
6.	Summary prepared:	06/07/02
7.	Proprietary name:	Q-Cath System
8.	Common name:	Physiological monitoring and analysis system
9.	Classification name:	§ 870.1425 Programmable diagnostic computer § 870.2050 Biopotential amplifier and signal conditioner § 870.2300 Cardiac monitor § 870.2340 Electrocardiograph

10. The Q-Cath System is substantially equivalent to the Quinton Q-Cath (K862740).

11. Description.
The Q-Cath system is a monitoring and analysis system that is used by Physicians, nurses, technicians and administrators associated with the cardiac catherization (cath) lab. The Q-Cath is a Microsoft Windows® based system with 32-bit architecture. The system contains an acquisition subsystem and an analysis subsystem. The Q-Cath organizes patient signals (invasive & non-invasive), and non-physiological signals from external devices. The Signal Conditioning System (SCS) acquisition subsystem contains connectors for the 12 lead surface ECG, four pressure inputs, three HIS inputs, two DC inputs, two types of synchronization waveform outputs and ECG simulator outputs. The optional Vital Statistical System (VSS) acquisition system contains module connections for the non-invasive blood pressure, the SPO2 and two auxiliary modules. The analysis system generates data based upon pressure site locations, ECG data and the entry of information such as cardiac output, oximetry results, and the patient physiological condition. The system stores Full Disclosure data of all waveform data to the Q-Cath local computer or can be stored off-line to a file server.

12. Intended use:
- The device is intended to monitor, analyze, document, and report hemodynamic data acquired during a cardiac catherization procedure.

- The system contains an acquisition subsystem and an analysis subsystem.
- The system acquires non-invasive and invasive data parameters. The data is received, displayed, stored, and analyzed in the Q-Cath.
- The device is to be used on adult and pediatric patients while undergoing a cardiac catherization procedure.
- Patient demographics, registration, patient assessment, procedure log notes, collected physiological and other Q-Cath data can be exported to an information management system.
- A Q-Cath remote workstation may be used to access patient files off-line or for the entering of additional patient information or editing of existing patient files. Additionally, the workstation may be used as a means of recording non-invasive vital signs data through the use of qualified third party peripheral monitoring devices.
- Multiple Q-Cath systems and workstations may be used and connected to a local area network.
- The Q-Cath system is not intended to be the sole means for monitoring a patient's status.

13. Technological comparison.
Both devices are based on personal computer (PC) platforms. The predicate device utilized a Pentium II processor while the proposed device utilizes a Pentium microprocessor or equivalent. Both devices utilize the same acquisition and analysis subsystems. Both devices utilize the same image analysis application. The predicate device utilizes a second PC for the image analysis application, these separate PC's share the same keyboard and monitor using a switch box to navigate between the two applications. The proposed device will allow the image analysis system to be co-resident on the PC. This represents a clinical process improvement and has no impact on the safety and/or efficacy of the device. The Windows based operating system is used in lieu of MS-DOS on the predicate device. This is a proven performance improvement in addition to providing a friendlier user environment. Material differences between the two devices are consistent with design. Both devices perform equivalently. Additionally, the proposed device has the capability to record non-invasive patient vital signs data outside of the cath lab (holding and recovery areas), to integrate image analysis reports into the cath final reporting, and to import patient registration, assessment, and clinical lab values from an external system. This represents a clinical process and workflow improvement and has no impact on the safety and/or efficacy of the device. Sterilization is not required for either device. Both devices utilize biocompatible materials that come into contact with the patient (patient leads). Mechanical safety, aside from stability, is not applicable for either device. Stability testing of both devices shall be performed in accordance with IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety. Chemical safety is not applicable for either device. Both devices are used in identical anatomical sites. Human factors for both devices are similar. Generated data is identical. However, the proposed device allows the user to import patient registration, assessment, clinical lab values, and image analysis reports from an external system. These enhancements to the application's workflow has no affect on safety and/or efficacy of the device. Both devices utilize medical grade power supplies to isolate the patient. The devices are for monitoring only. No energy is delivered to the patient. Both devices shall be compatible with their intended environment. The predicate device complied to IEC

801 Electromagnetic compatibility and CISPR 11 Industrial, scientific, and medical equipment – Electromagnetic disturbance characteristics – Limits and methods of measurement, now components of IEC 60601-1-2. Electromagnetic emission compliance for the proposed device is ensured in accordance with IEC 60601-1-2 Medical Electrical Equipment – Part 1: General Requirements for Safety: Electromagnetic Compatibility – Requirements and Tests. Both devices shall be used in a clinical or hospital environment. Electrical safety of both devices is assured by compliance with IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety. Thermal safety of both devices is assured by compliance with IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety. Ionizing energy is not emitted by either device. The proposed device is substantially equivalent in safety and effectiveness to the Quinton Q-Cath.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 4 2002

Quinton, Inc.
c/o Ms. Karen Browne
Director, Quality Assurance and Regulatory Affairs
3303 Monte Villa Parkway
Bothell, WA 98021-8906

Re: K021906
Trade Name: Q-Cath System
Regulation Name: Programmable Diagnostic Computer
Regulation Number: 21 CFR 870.1425
Regulatory Class: Class II (two)
Product Code: DQK
Dated: June 7, 2002
Received: June 10, 2002

Dear Ms. Browne:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

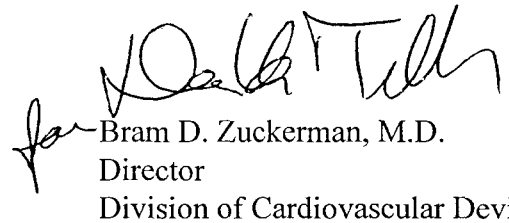
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Q-Cath System

Indications For Use:

- The device is intended to monitor, analyze, document, and report hemodynamic data acquired during a cardiac catherization procedure.
- The system contains an acquisition subsystem and an analysis subsystem.
- The system acquires non-invasive and invasive data parameters. The data is received, displayed, stored, and analyzed in the Q-Cath.
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K021906

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)